

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: ALFUZOSIN HYDROCHLORIDE
PATENT LITIGATION

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) MDL No. 08-md-1941 (GMS)
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STIPULATION AND ORDER

1. WHEREAS, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "sanofi-aventis") filed actions for patent infringement in this Court against Defendants Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries, Ltd., Sun Pharma Advanced Research Company, and Sun Pharma Global, Inc. (collectively, "Sun") regarding Sun Pharmaceutical Industries, Ltd.'s Abbreviated New Drug Application No. 79-057 ("ANDA 79-057") as filed June 12, 2007 and the proposed generic product defined therein, *sanofi-aventis v. Actavis South Atlantic LLC, et al.*, Civil Action No. 07-572 (D. Del.) ("the '940 Sun Action") and *sanofi-aventis v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 08-350 (D. Del.) ("the '491 Sun Action"), (collectively, the "Sun Actions"), which actions were consolidated for pretrial proceedings with other related suits by the Judicial Panel of Multidistrict Litigation, *In re Alfuzosin Hydrochloride Patent Litigation*, MDL No. 08-md-1941 (D. Del.) (the "MDL Action").
2. WHEREAS, in the Sun Actions, sanofi-aventis alleged that Sun Pharmaceutical Industries, Ltd.'s submission of ANDA 79-057 to the U.S. Food and Drug Administration and the § 505(j)(2)(A)(vii)(IV) allegations contained therein constituted infringement of U.S. Patent

No. 4,661,491 ("the '491 patent") and U.S. Patent No. 6,149,940 ("the '940 Patent") in its Complaints, filed September 21, 2007 and June 11, 2008 (the "Complaints").

3. WHEREAS, in response to sanofi-aventis's charge of patent infringement, Sun has alleged defenses and counterclaims, including, *inter alia*, that the '491 patent and the '940 patent are invalid and not infringed by the generic extended release 10 mg alfuzosin hydrochloride tablets defined in ANDA 79-057, in its Answers, filed October 29, 2007 and July 14, 2008 (the "Answers"). No decision has been obtained by the parties from this Court regarding either sanofi-aventis's claims of infringement or Sun's defenses and counterclaims.
4. WHEREAS, sanofi-aventis and Sun agree that sanofi-aventis's claims related to the '940 patent and Sun's declaratory judgment counterclaims related to the '940 patent should be dismissed with prejudice. This dismissal shall have no impact on sanofi-aventis's ability to assert claims against Sun under the '940 patent should Sun amend the formulation described in ANDA 79-057 as filed on June 12, 2007 ("Sun's ANDA Formulation") to change its composition or manufacturing method, except for any Level 1 changes permitted under the United States Food and Drug Administration's ("FDA") Guidance for Industry SUPAC-MR: Modified Release Solid Oral Dosage Forms (September 1997), or file a supplement to ANDA 79-057 or a wholly separate ANDA, so long as sanofi-aventis in good faith believes that such amendment to the formulation or supplement to ANDA 79-057 or wholly separate ANDA infringes the '940 patent; nor shall it have any impact upon Sun's ability to raise defenses or counterclaims in response to any such claims asserted by sanofi-aventis.
5. WHEREAS, pursuant to sanofi-aventis's reporting obligations to the Federal Trade Commission ("FTC") under the Decision and Order, *In re Hoechst Marion Roussel*, FTC Dkt. No. 9293 (May 8, 2001), this agreement is subject to prenotification to the FTC prior to

its effective date, said effective date shall be the date that it is filed with the Court which will be thirty (30) days after it is submitted to the FTC.

6. WHEREAS, sanofi-aventis and Sun agree to stay the Sun Actions with respect to sanofi-aventis's claims and Sun's declaratory judgment counterclaims relating to the '491 patent.

Further, with respect to the '491 patent:

- (a) if a judgment in favor of sanofi-aventis is entered in the MDL Action, the stay shall be lifted and such a judgment shall be entered in the Sun '491 Action at the same time;
- (b) if a judgment of invalidity is entered in the MDL Action, the stay shall be lifted and such a judgment shall be entered in the Sun '491 Action at the same time;
- (c) if a judgment of unenforceability is entered in the MDL Action, the stay shall be lifted and such a judgment shall be entered in the Sun '491 Action at the same time;
- (d) if a judgment of non-infringement is entered in the MDL Action based on a finding that the claims of the '491 patent do not cover the use for which Uroxatral® has been approved by FDA, the stay shall be lifted and such a judgment shall be entered in the Sun '491 Action at the same time;
- (e) any judgment entered in favor of sanofi-aventis as a result of a judgment in the MDL Action may be appealed by the Sun entities on the record in the MDL Action;
- (f) any judgment entered in favor of Sun as a result of a judgment in the MDL Action shall be subject to appeal by sanofi-aventis in that Action;
- (g) in the event that judgment in favor of sanofi-aventis is not appealed by Sun, but is vacated, modified, affirmed or reversed on appeal in the MDL Action, then such

judgment shall be applied in the same manner to any judgment entered in the Sun Actions;

- (h) in the event the MDL action is terminated prior to final judgment, by reason of settlement or otherwise, the stay shall be lifted and the parties shall be free to litigate any remaining claims or counterclaims on the '491 patent in the Sun Actions; and
- (i) in the event that Sun intends to launch its generic product prior to the expiration of the '491 Patent, including all extensions and marketing exclusivities, including but not limited to patent term extensions or pediatric exclusivities, Sun shall provide sanofi-aventis with 60 days notice of their intent to launch, the stay shall be lifted, and sanofi-aventis shall be free to seek injunctive relief to prevent the launch of Sun's generic product.

IT IS HEREBY STIPULATED by sanofi-aventis and Sun, subject to the approval of the Court, it is hereby ORDERED that:

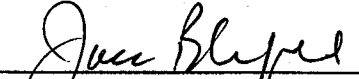
1. Sanofi-aventis's claims related to the '940 patent and Sun's declaratory judgment counterclaims related to the '940 patent are dismissed with prejudice subject to sanofi-aventis reinstating such claims pursuant to Section 4 above.
2. The Sun Actions are stayed with respect to sanofi-aventis's claims and Sun's declaratory judgment counterclaims relating to the '491 patent, pending entry of judgment in the MDL Action or termination of the MDL Action, which judgment shall be entered in the Sun Action as described in Section 6, above.
3. Notwithstanding entry of a final judgment in the MDL Action concerning the issues of willful infringement and/or exceptional case under 35 U.S.C. § 285, no such judgment shall be entered in the Sun Actions, both parties having agreed to waive any claim for attorney's

fees and costs against the other in the Sun Actions; however this clause shall have no effect with respect to the '491 patent claims and counterclaims if such claims are litigated following the stay being lifted pursuant to Section 6(h)-(i) above.

4. This Court retains jurisdiction over sanofi-aventis and Sun for purposes of enforcing this Stipulation and Order.

DATED: June 25, 2009

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

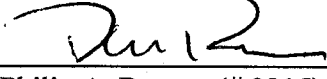

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SO ORDERED:

This _____ day of _____, 2009

**HONORABLE GREGORY M. SLEET
UNITED STATES DISTRICT JUDGE**